# 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**The assigned 510(k) number is:** K001620

**Applicant information:**

| | |
|---|---|
| Date Prepared: | May 23rd, 2000 |
| Name: | **Metro Optics of Austin, Inc.** |
| Address | 15802 Vision Drive<br>Pflugerville, TX 78660 |
| Contact Person: | Mr. Steve WEbb |
| Phone number: | (512) 251-2382 |
| USA Consultant: | Medvice Consulting, Inc.<br>Martin Dalsing |
| Phone number | (970) 243-5490 |

**Device Information:**

| | |
|---|---|
| Device Classification: | Class II |
| Classification Number: | LPL |
| Classification Name: | Lenses, Soft Contact, Daily Wear |
| Trade Name: | **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)** |

**Equivalent Devices:**

The **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lens** is substantially equivalent to the following predicate devices in terms of intended use and design. Predicate devices include:

| Soft Contact Lens | Manufacturer |
|---|---|
| 1. UCL Multifocal Toric | United Contact Lens |
| 2. OCU-FLEX 53 | Ocu-Ease Optical |
| 3. HORIZON 55 BI-CON TORIC | Westcon Contact Lens |

**Device Description:**

The **MetroFocal Toric (polymacon) Soft Daily Wear Contact Lenses** are fabricated from polymacon, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The **MetroFocal Toric (polymacon) Soft Contact Lenses** are available as a multifocal lens with a spherical front surface and aspherical back surface serving two functions; the correction of visual acuity in persons who possess refractive astigmatism not exceeding 10 diopters and are presbyopic. The MetroFocal is designed with a spherical central zone for distance and an aspherical progressive add multifocal zone, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength. The lenses are available in clear and with a blue visibility-handling tint, phthalocyanato (2) - (copper). The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

| | |
|---|---|
| **Refractive Index** | 1.52 (dry) 1.43 (hydrated) |
| **Color Pigment Name** | Phthalocyanine Blue |
| **Light Transmission (clear)** | greater than 95% T |
| **Light Transmission (tinted)** | greater than 95% T |
| **Water Content** | 38 % ± 2% |
| **Specific Gravity** | 1.328 (dry) 1.18 (hydrated) |
| **Oxygen Permeability** | **Dk** = 9X $10^{-11}$ ($cm^2$/sec) (ml $O_2$/ml x mm Hg @ 35°C), (revised Fatt method). |

**Intended Use:**

The **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters and are presbyopic. The lens may be disinfected using a chemical system and is available in a planned replacement Program.

**Substantial Equivalence:**

The device will be manufactured according to specified process controls and a quality assurance program. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently manufactured, marketed and distributed by Metro Optics. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 5X, 510(k) K952620. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates that the production method, lens function and material of the **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lenses** are substantially equivalent to the predicate devices. In addition, the water content, polymer, DK value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate devices.

**Substantial Equivalence Matrix**

| | Substantial Equivalency | MetroFocal Toric | UCL Multifocal (predicate device) | Horizon 55 BICON (predicate device) |
|---|---|---|---|---|
| 1.) | Intended Use | Daily wear, Soft (hydrophilic) contact lens, for the presbyopic patient | Daily wear, Soft (hydrophilic) contact lens, presbyopic | Daily wear, Soft (hydrophilic) contact lens, presbyopic |
| 2.) | Indication | Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia aand are presbyopic | Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia aand are presbyopic | Correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia aand are presbyopic |
| 3.) | DESIGN | **Simultaneous Vision** Multifocal (distance, intermediate, near) | **Simultaneous Vision** Multifocal (distance, intermediate, near) | **Simultaneous Vision** Bifocal (distance, near) |
| 4.) | LENS FUNCTION | Refractive medium that focus light rays from distant, intermediate and near objects on the retina, while compensating for refractive error. | Refractive medium that focus light rays from distant, intermediate and near objects on the retina, while compensating for refractive error. | Refractive medium that focus light rays from distant, intermediate and near objects on the retina, while compensating for refractive error. |
| 5.) | MATERIAL | hydrophilic (polymacon) | hydrophilic (ocufilcon C) | hydrophilic (methafilcon A) |
| 6.) | Dk Value | 9 | 18 8 | 18.8 |
| 7.) | PRODUCTION METHOD | Lathe-cut | Lathe-cut | Lathe-cut |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2000

Metro Optics of Austin, Inc.
c/o Mr. Martin Dalsing
Medvice Consulting Inc.
623 Glacier Drive
Grand Junction, Co 81503

Re: K001620
Trade Name: MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut form Lens Blank)
Regulatory Class: II
Product Code: 86 LPL
Dated: April 14, 2000
Received: April 17, 2000

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# INDICATIONS FOR USE STATEMENT

**Device Name:** **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

**INDICATIONS FOR USE:**

The **MetroFocal Toric (polymacon) Soft (Multifocal) Daily Wear Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters and are presbyopic. The lens may be disinfected using a chemical system and is available in a planned replacement Program.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)

Daniel W. C. Brown, PH. D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001620